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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/044,564	01/11/2002	Peter D. Mezes	21402-240	9486

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EXAMINER	
WAX, ROBERT A	

ART UNIT	PAPER NUMBER
1653	

DATE MAILED: 06/28/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/044,564	MEZES ET AL.	
	Examiner	Art Unit	
	Robert A. Wax	1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-64 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-64 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-5, 9, 13, 49-52 and 64, drawn to methods of treating or delaying the onset of an angiogenic-associated disorder (claims 1-5), a method of treating a pathological state in a mammal (claims 9 and 64), a method of treating or delaying the onset of a disorder (claim 13), and a method of treating or preventing a Novx-associated disorder (claims 49-52), said method comprising administering to a subject in need thereof an antibody to the polypeptide of SEC1, SEC2, SEC3, SEC4, SEC5, SEC6, SEC7, SEC8, SEC9, SEC10, SEC11, or SEC12, classified in class 424, subclass 139.1.

II. Claims 6, 7, 15, 33, 37-39, 59 and 60, drawn to methods involving detection of one of the polypeptides SEC1, SEC2, SEC3, SEC4, SEC5, SEC6, SEC7, SEC8, SEC9, SEC10, SEC11, or SEC12, classified in class 435, subclass 7.1.

III. Claims 8, 10-12, 14, 40-44 and 63, drawn to methods of treatment comprising administration of one of the polypeptides SEC1, SEC2, SEC3, SEC4, SEC5, SEC6, SEC7, SEC8, SEC9, SEC10, SEC11, or SEC12, classified in class 514, subclass 12.

IV. Claims 16-19, 53 and 56, drawn to a polypeptide selected from SEC1, SEC2, SEC3, SEC4, SEC5, SEC6, SEC7, SEC8, SEC9, SEC10, SEC11, or SEC12 and pharmaceutical compositions thereof, classified in class 514, subclass 12.

V. Claims 20-29, 54 and 57, drawn to DNA, vector and host cell, classified in class 435, subclass 252.3.

VI. Claims 30-32, 55 and 58, drawn to antibodies to a polypeptide selected from SEC1, SEC2, SEC3, SEC4, SEC5, SEC6, SEC7, SEC8, SEC9, SEC10, SEC11, or SEC12 and pharmaceutical compositions thereof, classified in class 424, subclass 139.1.

VII. Claims 34-36, 61 and 62, drawn to method of detecting DNA, classified in class 435, subclass 6.

VIII. Claims 45-48, drawn to method of treating or preventing a NOVX-associated disorder comprising administration of DNA, classified in class 514, subclass 44.

The inventions are distinct, each from the other because of the following reasons:

2. Inventions I and (II-V, VII and VIII) are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the treatment methods using antibodies of Group I

and the methods of Groups II-V, VII and VIII do not require each other for their practice; have separate utilities, are physically, chemically and biologically different from each other; and are subject to separate manufacture and sale from each other. These groups have acquired separate status in the art and separate fields of search as further evidenced by their separate classification.

3. Inventions I and VI are related as process of use and product. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the antibodies of Group VI may be used in a materially different process of use such as immunoassay to detect the presence of the protein.

4. Inventions II and (III and V-VIII) are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the methods involving detection of protein of Group I and the methods and products of Groups (III and V-VIII) do not require each other for their practice; have separate utilities, are physically, chemically and biologically different from each other; and are subject to separate manufacture and sale from each other. These groups have acquired separate status in the art and separate fields of search as further

evidenced by their separate classification.

5. Inventions II and IV are related as process of use and product. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product as claimed can be used in a materially different process such as treatment methods.

6. Inventions III and IV are related as process of use and product. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product as claimed can be used in a materially different process such as methods involving detection of protein.

7. Inventions III and V-VIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the treatment methods using the protein of Group III and the methods and products of Groups V-VIII do not require each other for their practice;

have separate utilities, are physically, chemically and biologically different from each other; and are subject to separate manufacture and sale from each other. These groups have acquired separate status in the art and separate fields of search as further evidenced by their separate classification.

8. The protein of group IV is related to the DNA of group V by virtue of the fact that the DNA codes for the protein. The DNA molecule has utility for the recombinant production of the protein in a host cell. Although the DNA and the protein are related, since the DNA encodes the specifically claimed protein, they are distinct inventions because the protein product can be made by other and materially distinct processes, such as purification from the natural source. Further, DNA can be used for processes other than the production of protein, such as nucleic acid hybridization assays.

9. Inventions IV and VI-VIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the proteins of Group IV and the methods and products of Groups VI-VIII do not require each other for their practice; have separate utilities, are physically, chemically and biologically different from each other; and are subject to separate manufacture and sale from each other. These groups have acquired separate status in the art and separate fields of search as further evidenced by their separate classification.

10. The DNA of group V and the antibodies of group VI are related by virtue of the proteins that are encoded by the various DNA molecules and are necessary for the production of the antibodies. However, the DNA itself is not necessary for antibody production and both are wholly different compounds having different compositions and functions. Therefore, these inventions are distinct.

11. Inventions V and (VII and VIII) are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product as claimed can be used in a materially different process such as evaluating the level of genetic diversity between two organisms.

12. Inventions VI and (VII and VIII) are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the antibodies of Group VI and the methods of Groups VII and VIII do not require each other for their practice; have separate utilities, are physically, chemically and biologically different from each other; and are subject to separate manufacture and sale from each other. These groups have acquired separate

status in the art and separate fields of search as further evidenced by their separate classification.

13. Inventions VII and VIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the methods involving detection of DNA of Group VII and the treatment method involving administration of DNA of Group VIII do not require each other for their practice; have separate utilities, are physically, chemically and biologically different from each other; and are subject to separate manufacture and sale from each other. These groups have acquired separate status in the art and separate fields of search as further evidenced by their separate classification.

14. Furthermore, in claims 13-64, the presence of multiple polypeptide sequences and polynucleotide sequences, each with a different SEQ ID NO: allows for a variety of patentably distinct products. Depending on the sequence of each polypeptide and polynucleotide, the characteristics of the resulting molecule will vary in regards to structure and function. Each one of these polypeptides is capable of eliciting a specific immune response and can be used to produce a specific antibody; also each one of the mentioned polynucleotides is capable of hybridizing to different probes and is capable of encoding a characteristically different peptide in regards to structure and activity. Therefore these polypeptides and polynucleotides are patentably distinct absent factual

evidence to the contrary. Applicant is required under 35 U.S.C. 121 to elect a single SEQ ID NO: for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. THIS IS NOT AN ELECTION OF SPECIES BUT A SECOND LEVEL OF RESTRICTION BETWEEN PATENTABLY DISTINCT INVENTIONS.

Applicant is advised that a reply to this requirement must include an identification of one of the polypeptides selected from SEC1-SEC12, including the appropriate SEQ ID No. that is elected consonant with this requirement, or an identification of the SEQ ID No. of DNA that is elected consonant with this requirement and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

15. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

16. A telephone call was made to Gregory Sieczkiewicz on June 8, 2004 to request an oral election to the above restriction requirement, but did not result in an election being made.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

17. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

18. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert A. Wax whose telephone number is (571) 272-0623. The examiner can normally be reached on Monday through Friday, between 9:00 AM and 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon P. Weber can be reached on (571) 272-0925. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Robert A. Wax
Primary Examiner
Art Unit 1653